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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/340,283	06/25/1999	ROBERT O. MESSING	GALO-007/01U	3708

7590 02/13/2002
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EXAMINER

SHUKLA, RAM R

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 02/13/2002

21

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/340,283

Applicant(s)

MESSING ET AL.

Examiner

Ram R Shukla

Art Unit

1632

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 14 January 2002 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☒ The period for reply expires 4 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
 - (b) ☒ they raise the issue of new matter (see Note below);
 - (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: None.

Claim(s) objected to: None.

Claim(s) rejected: 10, 29, 31-33 and 35-39.

Claim(s) withdrawn from consideration: 1-9, 11-28, and 40-53.

8. ☐ The proposed drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. ☐ Other: _____

Continuation of 2. NOTE: Proposed amendments to claims 32 and 35 recite the phrase "measuring the activity of PKC epsilon" and "wherein said measuring is performed in other than an animal", which are broader in scope compared with the originally presented claim. The phrase "measuring the activity of PKC epsilon" replaces the term "exposing a functionally PKC epsilon to a test compound" which do not encompass the same step and therefore the proposed phrase was not considered previously and would require further consideration and search. The phrase wherein said measuring is performed in other than an animal is a new limitation which was not considered previously and since it encompasses limitations of just in animal or in vitro, it would also require new consideration and new search. Additionally, this phrase also raises the issue of new matter since there is no support for the phrase in the specification. It is noted that the applicants did not indicate as to where in the specification the phrase is disclosed.

Continuation of 5. does NOT place the application in condition for allowance because: Applicants' arguments have been considered, however they are not persuasive. It is noted that several enablement issues were raised in the previous office actions which were summarized on pages 3-4 of the previous office action of 9-13-01, the major issue being: lack of clear evidence that changes in change in PKC-epsilon is responsible for anxiety level changes due to the differences in male and female mice and what would be a suitable test subject for screening drugs that modulate PKC-epsilon and alter anxiety. It is reiterated that specification describes that in PKC-epsilon null mice, there is reduced level of anxiety which is an extreme situation since there is no evidence of record to indicate that under conditions of high or low anxiety, there is alteration in PKC-epsilon levels of an animal whether it is a normal animal or an animal model of anxiety. Applicants arguments fail to address this issue rather they reiterate their results with the mutant mice. Regarding other issues, arguments seem to be reiterations of the arguments made in response to the previous office actions. Applicants have repeatedly argued that animal or subject models for anxiety are known in the art and have attached two articles in support, however these arguments do not address the issue raised in the previous office action that there is considerable difference in the parameters of anxiety even among different inbred strain of mice, therefore, in the absence of any correlatory step of PKC-epsilon activity and anxiety parameter in the method, an artisan would not know whether the change in an anxiety parameter is due to PKC-epsilon activity modulation or due to variations observed normally. Application argue that this is not important for the method to work, however, the argument is not persuasive because the anxiety modulatory compound of the instant invention is characterized by its modulation of PKC-epsilon activity. Accordingly, the enablement rejections are maintained for reasons of record set forth in the previous office actions of 12-18-00 and 9-13-01.



DAVE T. NGUYEN
PRIMARY EXAMINER